

Randomized- blind cross-over trial.

Patients with active CD were given azathioprine 4 mg/kg/d for 10 days and thereafter 2mg/kg/d for 2 months and placebo for 2 months the sequence of the 2 treatment was randomized.

Primary endpoints: Improvement after 2 month therapy.

Results: N=15

- Change in symptoms at 2 months: AZA period 7/15 patients did not have a change in symptoms and 11/15 placebo.

Conclusion:

Azathioprine was not better than placebo to induce improvement in active CD.

TABLE III—ASSESSMENT OF THE PATIENTS' CLINICAL PROGRESS IN THE TWO TREATMENT PERIODS

Patient no.	Patients' assessment of change in symptoms in:		Physicians' assessment with clinical comment
	Period I	Period II	
<i>Azathioprine first:</i>			
1	None	Better	Well throughout; fistulous discharge a little less in II
2	None	None	Ill; copious fistulous discharge which decreased a little in first 2 weeks of I
3	Worse	Better	Fairly well; moderate fistulous discharge which increased in I
5	None	None	Unwell; much discharge from perianal area—possibly improved a little in I
7	None	None	Well throughout trial
8	None	None	Well throughout trial
11	None	None	Quite ill throughout trial
12	Worse	?Better	Very ill; minimal improvement at the beginning of II
<i>Placebo first:</i>			
4	None	Better	Well; moderate fistulous discharge which improved considerably in II
6	None	Worse	Fairly well; little change in clinical state
9	None	Worse	Moderately unwell; little apparent change in the 4 months
10	None	Worse	Ill; much worse in II with severe colic and vomiting
13	None	Better	Moderately unwell; possibly a little improvement in I but definite improvement in II
14	None	None	Fairly well; no change during trial
15	Worse	Much worse	Very ill; gradual deterioration throughout; much worse in II with fever and arthralgia

I and II are abbreviations for period I and period II.

"None" = no change in clinical symptoms.

"Better" = patient improved in that period.

"Worse" = patient deteriorated in that period.

